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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,575	02/27/2002	Muraleedharan G. Nair	NP4039.P2	9173

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[REDACTED] EXAMINER

TATE, CHRISTOPHER ROBIN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1654

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>10/084,575</b>	Applicant(s) <b>Nair et al.</b>
	Examiner <b>Christopher Tate</b>	Art Unit <b>1654</b>



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on Jun 12, 2003
- 2a)  This action is FINAL.      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 12-27 and 57-60 is/are pending in the application.
- 4a) Of the above, claim(s) 15, 16, 18, 19, 21, 25-27, and 57-60 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 12-14, 17, 20, and 22-24 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Applicants' election without traverse of Group II, claims 12-27, in Paper No. 6 is acknowledged. In addition, Applicants' election of the plant species elderberry and the anthocyanidin compound species cyanidin-3-sambubioside are also acknowledged. Applicants state that claims 12, 13, 14, 17, 20, 22-24 and new claims 57-60, are readable upon these species. However, claims 57-60 are drawn to particular combinations of two or more plants (see, e.g., first paragraph on page 6 of the previous Office action) and, thus, do not read upon the elected species (the singular elderberry plant). Accordingly, claims 15, 16, 18, 19, 21, 25-27 and 57-60 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 12, 13, 14, 17, 20, 22-24 are presented for examination on the merits. Please note that these claims have only been examined over the art insofar as they read upon the elected invention (i.e., a method of alleviating or reducing pain or symptoms of pain in a mammal in need thereof via providing an effective amount of an elderberry extract thereto).

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 14, 17, 20, and 22-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 12, 20, and 23 are rendered vague and indefinite by the phrase "providing an effective amount ... to a mammal". It is unclear by this phrase if the mammal actually is being administered the claimed extract - i.e., the ambiguous term "providing" is subject to various interpretations (e.g., "providing" could simply mean providing a bottle containing an effective amount of the extract solution to the mammal without actually administering it to the mammal). It is, therefore, suggested that the term "providing" be omitted and replaced with --administering-- within the independent claims, as well as any other instance this term may appear in the claims.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 12, 13, 14, 17, 20, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by the Internet publication titled "Elixir of Elderberry" (MotherNature.com; first published on internet in 1995), by the Internet publication titled "Sambucol Black Elderberry" (MotherNature.com; first published on the internet in 1995), by Keville (Vegetarian times, 1990), by Brown (Tom Brown's Guide to Wild Edible and Medicinal Plants, 1985), by Hirschhorn (The Home Herbal Doctor, 1982), or by Tanaka et al. (JP 07101836 - JPAB Abstract, 1995).

A method of alleviating or reducing pain in a mammal via providing an effective amount of an elderberry extract is claimed.

Each of the cited references teach therapeutic elderberry extract preparations (thus, being provided to mammals) which is used for treating pain such as back/muscle pain, rheumatism/rheumatic pain, and/or headaches (see, e.g., Descriptions in the MotherNature internet publications; pages 62-65 of Keville; pages 115-117 of Brown; pages 52-53 of Hirschhorn; and the JP Abstract by Tanaka et al.). Although not expressly taught, please note that each of these extracts would inherently comprise naturally-occurring cyanidin-3-sambubioside therein.

Therefore, each of the cited references is deemed to anticipate the instant claims above.

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***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 13, 14, 17, 20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Internet publication titled "Elixir of Elderberry" (MotherNature.com; first published on internet in 1995), the Internet publication titled "Sambucol Black Elderberry" (MotherNature.com; first published on the internet in 1995), Keville (Vegetarian times, 1990), Brown (Tom Brown's Guide to Wild Edible and Medicinal Plants, 1985), Hirschhorn (The Home Herbal Doctor, 1982), and Tanaka et al. (JP 07101836 - JPAB Abstract, 1995).

The references are relied upon for the reasons discussed *supra*. If not expressly taught, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer an effective amount of one or more of the elderberry extract preparations taught by the cited references to a mammal experiencing pain based upon the clear beneficial teachings provided therein with respect to the pain-relieving activity such elderberry extract preparations afford. Again, please note that reference elderberry extracts would intrinsically comprise naturally-occurring cyanidin-3-sambubioside therein.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate  
Primary Examiner, Group 1654